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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,391	02/26/2002	Gregory Gene Steiner		8379

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EXAMINER	
COOK, REBECCA	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,391	STEINER, GREGORY GENE	
	Examiner	Art Unit	
	Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the incidence of cancer, does not reasonably provide enablement for preventing cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to prevention of any and all cancer, and the relative skill of those in the art is high, generally that of a PHD or MD. This unpredictability has a number of facets, as discussed hereinafter.

A. Treatment by Cancer Type

While the state of the art is relatively high with regard to the prevention of specific cancer with specific agents, it has long been underdeveloped with regard to the prevention of cancer broadly. In particular, there is no known agent which is effective to prevent all cancer. This is why the National Cancer Institute (NCI) has the extensive *in vitro* drug screening program it does. As discussed by the court in In re Brana, 51 F.3d 1560 (Fed. Cir. 1995), *in vitro* assays are used by NCI (such as the P388 and L1210 lymphocytic leukemia tests at issue therein) to measure the potential antitumor properties of a candidate compound. Brana at 1562-63. If success is shown in this initial screening step, this demonstrates that at least one cancer type (e.g., lymphocytic leukemia) is sensitive thereto, and provides the incentive to select it for further studies to determine its usefulness as a chemotherapeutic agent against other cancer types (lung, breast, colon, etc.) *Id.* at 1567-68. These *in vitro* tests are considered reasonably correlative of success *in vivo*.

Thus, a considerable amount of *in vitro* empirical testing is required, with no *a priori* expectation of success being present, before a candidate anticancer agent can be considered useful to prevent any and all cancer.

2. The breadth of the claims

The claims are very broad and inclusive of prevention of all "cancers" generally. The term "prevention' can be construed broadly as either prevention the onset of clinically evident cancer altogether or preventing the onset of a preclinically evident stage of neoplasia in individuals at risk. In other words, the instant claims are drawn to a composition and method of preventing all preclinical stages of any and all stages of cancers, which includes any undetectable stages of cancer.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction for ascertaining, *a priori*, which cancer will be prevented. It is known in the art that various factors are involved in causing various cancer, including genetics and environmental factors, such as diet and exposure to carcinogens.

4. The quantity of experimentation necessary

The lack of adequate guidance from the specification or prior art with regard to the actual prevention of all cancers in a mammal with the claimed compounds fails to rebut the presumption of unpredictability extant in this art. Applicants fail to provide the guidance and information required to ascertain which particular cancers the claimed agents will be effective against without resorting to undue experimentation. Applicant's limited disclosure of cancer incidence rate and kilograms of kava consumer per person on page 12 is noted, but is not sufficient to claiming prevention of all cancers broadly.

Absent a reasonable *a priori* expectation of success for using a specific combination to treat any particular type of cancer, one skilled in the art would have to

extensively test many various tumor types. Since each prospective embodiment, and indeed future embodiments as the art progresses, would have to be empirically tested, and those which initially failed tested further, an undue amount of experimentation would be required to practice the invention as its is claimed in its current scope, because the specification provides inadequate guidance to do otherwise.

Amending the claims to recite "A method of reducing the incidence of cancer..." or "lowering the incidence of cancer" instead of "preventing" would overcome this rejection.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear whether compounds 4-13 and 15 disclosed on pages 7-8 of the specification are still intended to be included in the alpha-pyrone compounds of the method claim 1 as now recited.

In claims 2-5 the recitation "the method of claim 1, comprising a [pill, etc.]" is confusing, since it is the composition that is in the forms recited in claims 2-5. Amending the claims to recite "in which the composition is in the form of a pill [etc]". will overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by CAPLUS DN 131:298760 (Fujiki). The reference (abstract) discloses that the kava is useful to prevent cancer. Claim 1 differs over Fujiki in reciting a specific alpha-pyrone compound. However, it would be inherent that kava would contain the recited compound, since it is a kava extract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over CAPLUS DN 131:298760. The reference (abstract) discloses that the kava is useful to prevent cancer. Claim 1 differs over the reference in reciting a specific alpha-pyrone compound. Claims 2-5 differ over the disclosure in reciting specific dosage forms. However, it would be inherent that kava would contain the recited compound, since it is a kava extract.

Furthermore, once the method of use of a compound is known, it is within the skill of the artisan to determine the optimum dosage forms. Additionally, the dosage forms of claims 2-5 are well-known in the pharmaceutical art.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 124:220762. The reference (abstract) discloses that the pyrone compound goniothalamin is useful to treat cancer.

The instant claims differ over the disclosure in reciting a positional isomer of goniothalamin and dosage forms. However, in the absence of a showing of unexpected results comparing the closest instantly recited compound with goniothalamin no unobviousness is seen in using a positional isomer. In re Norris 84 USPQ 458.

Additionally, once the method of use of a compound is known, it is within the skill of the artisan to determine the optimum dosage forms. Moreover, the dosage forms of claims 2-5 are well-known in the pharmaceutical art.

In view of the amendments to claim 1 the earlier rejection under 35 USC 103(a) over Volz is withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 09/792,898. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '898 includes the compound of the instant method when R1 is methoxy.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. It is noted that Applicant did not argue this rejection.

Prior Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,981,496, CAPLUS DN 127:15310, CAPLUS AN 3:6189 and MEDLINE 93267261 disclose a method of using a pyrone derivative to treat cancer but do not render the instant invention obvious in the absence of additional information.

Applicant's comment regarding classification of the compound of the instant method is noted. However, the instant compound is not a polycyclo ring system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook

Primary Examiner
Art Unit 1614

October 24, 2005